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Remarks

Claims 1, 3-9, 11-23, and 26 are pending. Claims 1, 3-9, 11-23, and 26 have been rejected. Claims 1 and 15 have been amended. No new matter has been added. Claims 2-7, 10, 24-25, and 27-75 have been canceled. Reconsideration of the present claims is respectfully requested.

Claims 1, 3-9, 11-23, 26 and 75 have been rejected under 35 U.S.C. §112, second paragraph, "as being incomplete for omitting essential elements, such omission amounting to a gap between the elements." Claims 1, 3-9, 12, 14-19, 21-23 and 75 have been rejected under 35 U.S.C. §102(a & e) as being anticipated by Snyder (U.S. Patent No. 6,063,771). Claims 1, 3-9, 12, 14-19, 21-23 and 75 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Snyder in view of Kassebaum et al. (United States Patent No. 6,933,318) and Vermeer (U.S. Patent No. 5,653,970) and Kang et al. (United States Patent No. 6,106,815). Claims 1, 4-9, 11-23, 26 and 75 have been rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,727,228.

35 U.S.C. §112, second paragraph

Claims 1, 3-9, 11-23, 26 and 75 have been rejected under 35 U.S.C. §112, second paragraph "as being incomplete for omitting essential elements, such omission amounting to a gap between the elements." Claim 26 has been rejected under 35 U.S.C. §112, second paragraph, however, claim 26 does not contain "R" nor does it depend from claim 1. Therefore, Applicant believes that claim 26 was rejected in error. Without conceding to the Examiner's characterization and without prejudice, independent claim 1 has been amended. Applicant respectfully submits that the §112 rejections with respect to claim 1 be withdrawn. Similarly, Applicant requests that the §112 rejections be withdrawn with respect to the remaining claims as

these claims depend from claim 1.

**35 U.S.C. §102**

Claims 1, 3-9, 12, 14-19, 21-23 and 75 have been rejected under 35 U.S.C. §102(a & e) as being anticipated by Snyder. Applicant respectfully disagrees. Claim 1 requires one or more stabilizers wherein the stabilizers comprise one or more of the group consisting of polyvinyl methyl ether/maleic anhydride Decadiene crosspolymers and acrylates/aminoacrylates C10-30 Alkyl PEG-20 Itaconate copolymer. Snyder does not teach polyvinyl methyl ether/maleic anhydride Decadiene crosspolymers or acrylates/aminoacrylates C10-30 Alkyl PEG-20 Itaconate copolymer. Since Snyder does not teach all of the claimed elements, the rejection under 35 U.S.C. §102 with respect to claim 1 should be withdrawn. Similarly, the rejection with respect to claims 8, 9, 12, 14-19, and 21-23 should be withdrawn because these claims depend from claim 1.

**35 U.S.C. §103**

Claims 1, 3-9, 12, 14-19, 21-23 and 75 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Snyder (U.S. Patent No. 6,063,771) in view of Kassebaum et al. (United States Patent No. 6,933,318) and Vermeer (U.S. Patent No. 5,653,970) and Kang et al. (United States Patent No. 6,106,815). Applicant respectfully disagrees for at least the following reasons.

35 U.S.C. §103(a) recites:

[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991), MPEP 706.02(j).

Claim 1 (and its dependent claims) requires a solution comprising water and one or more stabilizers, wherein the stabilizers comprise one or more of the group consisting of polyvinyl methyl ether/maleic anhydride Decadiene crosspolymers and acrylates/aminoacrylates C10-30 Alkyl PEG-20 Itaconate copolymer. None of the cited references teach the use of acrylates/aminoacrylates C10-30 Alkyl PEG-20 Itaconate copolymer. Further, neither Snyder, Kassebaum nor Vermeer teach the use of PVM/MA decadiene crosspolymers. The Examiner has attempted to rely on Kang to fill this deficiency. Such reliance is misplaced.

Kang teaches the use of PVM/MA Decadiene crosspolymers for use as a dispersing agent in shampoo compositions containing "capsulated or particulated oily substances." See column 2, lines 35-39. In fact, the problem present in the prior art that Kang sought to address is that "capsules containing oily substances were unsatisfactorily dispersed in the shampoo systems. Specifically, using the patented techniques, it was impossible to stably disperse capsules containing oily substances, with the specific gravity of the capsules being 0.5-0.95 at 25°C., into the shampoo systems." See column 2, lines 17-24. Thus, according to Kang, the object of the invention is "to provide an improved shampoo composition in which capsules containing oily

substances are stably dispersed for a long period.” See column 2, lines 26-32.

Claim 1 requires a solution, thus Applicant’s claimed composition does not contain particles or capsules. There is no teaching or suggestion in Kang to use PVM/MA decadiene crosspolymer to stabilize *solutions*, as claimed by Applicant. Rather, the teachings of Kang are limited to the use of PVM/MA decadiene crosspolymer as a *dispersing agent* for “capsulated or particulated oily substances.” One of skill in the art would not find any suggestion to use PVM/MA decadiene crosspolymers in solutions based on the teachings of Snyder, Kassebaum, Vermeer or Kang because none of these discuss or even suggest the use of PVM/MA decadiene crosspolymers as stabilizers in solutions.

Further, given that neither Snyder nor Kassebaum nor Vermeer nor Kang teach or suggest the use of PVM/MA decadiene crosspolymers or acrylates/aminoacrylates C10-30 Alkyl PEG-20 Itaconate copolymer in solutions, one of skill in the art would not have a reasonable expectation of success that PVM/MA decadiene crosspolymers or acrylates/aminoacrylates C10-30 Alkyl PEG-20 Itaconate copolymer would be effective stabilizers for solutions. Moreover, as explained above, Applicant’s invention requires the use of either PVM/MA decadiene crosspolymers or acrylates/aminoacrylates C10-30 Alkyl PEG-20 Itaconate copolymer to stabilize a solution of one or more agents having pediculicidal and ovacidal properties for adult lice and nits of a specie of order Anoplura. The references cited by the Examiner, either alone or combined, fail to teach this limitation – the stabilization of a solution of specified active ingredients with PVM/MA decadiene crosspolymers or acrylates/aminoacrylates C10-30 Alkyl PEG-20 Itaconate copolymer.

In addition, one of skill in the art would not be motivated to combine the teachings of Snyder and Kassebaum with those of Kang and Vermeer because Snyder and Kassebaum deal

specifically with formulations for controlling lice while neither Kang nor Vermeer contemplate the use of shampoo for lice control. Rather, Kang is directed to shampoo compositions which are dispersions not solutions having "excellent conditioning and esthetic properties," *see* column 2, line 40, and Vermeer is directed to "personal product compositions that have improved foam, viscosity, clarity and conditioning characteristics due to the inclusion of a new type of alkyl aldonamide compound, specifically heteroatom containing alkyl aldonamide compounds." *See* column 1, lines 7-11. Thus, one concerned with treating lice would not look to references which do not contemplate the inclusion of lice medicaments nor any such treatment. Applicant respectfully requests that the §103 rejection with respect to claim 1 and its dependent claims be withdrawn because the Examiner has not established a prima facie case of obviousness.

#### **Long Felt Need and Unexpected Results**

While Applicant believes that the obviousness rejection has been overcome, assuming *arguendo* that there is a prima facie case of obviousness; Applicant notes that there was a long-felt need for the present invention. MPEP § 716.04. This long-felt need was "recognized, persistent and not solved by others." MPEP § 716.04. According to Applicant on page 2 of the specification, prior art methods and compositions are not entirely effective in lice treatment because lice often survive the prior art treatments. Additionally, in some countries (including the United States), "lice have begun to develop resistance to current pediculicides." (Specification, p.2) This long-felt need was not addressed in the prior art as is stated in the specification.

Further, Applicant's invention demonstrates unexpected results. Applicant notes in the application on pages 15-16, that the stabilizers used unexpectedly stabilize the solutions and "prevent physical separation of the formulation." The claimed stabilizers were not known to be used with the claimed agents for said stabilization in solution, and the Examiner has not offered

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any evidence to show this allegedly known use of the claimed stabilizers. Therefore, Applicant believes this and the other arguments above overcome the § 103 rejection.

**Nonstatutory Obviousness-Type Double Patenting**

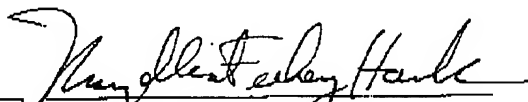
Claims 1, 4-9, 11-23, 26 and 75 have been rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,727,228. Without conceding to the Examining Attorney's characterization, Applicant agrees that if the claims are allowable, Applicant will submit a terminal disclaimer with respect to United States Patent No. 6,727,228.

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Conclusion

In view of the foregoing amendments and remarks, Applicant submits that the present claims are in condition for allowance. Should there be any fees due or any over-payment with respect to this submission or during the entire pendency of the application, the Commissioner is hereby authorized to charge any deficiency or credit any over-payment to Deposit Account No. 18-0586.


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I hereby certify that this paper and the papers referred to herein as being transmitted, submitted, or enclosed herewith in connection with U.S. Serial No. 10/726,241 is/are being facsimile transmitted to the United States Patent and Trademark Office fax number 571 273 8300 on the date shown below.



Maryellen Feehery Hank

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